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09/840,624	04/23/2001	Alastair McIndoe Hodges	MEMTEC.063C3	5099

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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/840,624	Applicant(s) HODGES ET AL
	Examiner ALEX NOGUEROLA	Art Unit 1753

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-25 and 27-32* is/are rejected.

7)☒ Claim(s) *18 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/852,804* and 09/068,828.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 and 4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Rejections - 35 USC § 112

1. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1 requires a sheet having a sample introduction aperture. Claim 9 requires a substantially flat strip having a sample introduction aperture or passage. It is not clear whether the sheet of claim 1 is also the strip of claim 9.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4-11, and 13-16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Diebold et al. (US 5,437,999).

Addressing claim 1, Diebold et al. teaches a biosensor for use in determining a concentration of a component in an aqueous liquid sample, the biosensor comprising

(a) an electrochemical cell, the electrochemical cell comprising a first electrically resistive substrate having a first thin layer of a first electrically conductive material on a first face, a second electrically resistive material on a second face, the substrates being disposed with the first electrically conductive material facing the second electrically conductive material and being separated by a sheet comprising an aperture, the wall of which aperture cooperates with the electrically conductive materials to define a cell wall, and wherein the aperture defines a working electrode area in the cell, the cell further comprising a sample introduction aperture whereby the aqueous liquid sample may be introduced into the cell; and

(b) a measuring circuit.

See the abstract and Figures 1-6; and col. 8, ll. 15-36.

Addressing claims 2 and 11, for the claimed socket region and contact areas note elements 41, 45, 9, and 3 in Figure 5.

Addressing claims 4 and 5, that the electrodes may be made of sputtered metal is taught in col. 3, ll. 50-65.

Addressing claims 6 and 7, it should first be noted that claims 6 and 7 of the instant application only provide for intended use. Thus, since these claims do not further structurally modify the invention of claim 1 of the instant application, the rejection of claim 1 above also apples to claims 6 and 7. In any event, Diebold et al. teach an embodiment especially adapted for measuring glucose in blood (col. 12, ln. 33 – col. 13, ln. 8).

Addressing claims 8 and 15, that the measuring circuit comprises an automated instrument for detecting an electrical signal from the electrochemical cell and relating the electrochemical signal to the concentration of the component in the aqueous sample is implied by col. 13, ll. 9-16, which teaches that the measuring circuit is adapted to apply an algorithm that relates the measured current to analyte concentration.

Addressing claims 9 and 16, a substantially flat strip having a notch through the entire thickness to form a sample introduction aperture or passage is shown in Figure 5 (elements 43, 44, and 49).

Addressing claim 10, Diebold et al. teaches a biosensor for use in determining a concentration of a component in an aqueous liquid sample, the biosensor comprising

(a) a thin layer electrochemical cell, the cell comprising

(i) an electrically resistive sheet comprising an aperture wherein the aperture defines a working electrode area in the cell;

(ii) a first electrode layer covering the aperture on a first side of the sheet;

(iii) a second electrode layer covering the aperture on a second side of the sheet; and

(b) a measuring circuit.

See the abstract; Figures 1-6; and col. 8, ll. 15-36.

Addressing claims 13 and 14, it should first be noted that claims 13 and 14 of the instant application only provide for intended use. Thus, since these claims do not further structurally modify the invention of claim 10 of the instant application, the rejection of claim 10 above also applies to claims 13 and 14. In any event, Diebold et al. teaches an embodiment especially adapted for measuring glucose in blood (col. 12, ln. 33 – col. 13, ln. 8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Dietze et al. (US 5,282,950).

Addressing claim 3, Diebold et al. teaches a biosensor for use in determining a concentration of a component in an aqueous liquid sample, the biosensor comprising

(a) an electrochemical cell, the electrochemical cell comprising a first electrically resistive substrate having a first thin layer of a first electrically conductive material on a first face, a second electrically resistive material on a second face, the substrates being disposed with the first electrically conductive material facing the second electrically conductive material and being separated by a sheet comprising an aperture, the wall of which aperture cooperates with the electrically conductive materials to define a cell wall, and wherein the aperture defines a working

electrode area in the cell, the cell further comprising a sample introduction aperture whereby the aqueous liquid sample may be introduced into the cell; and

(b) a measuring circuit.

See the abstract and Figures 1-6; and col. 8, ll. 15-36.

Although Diebold et al. disclose connecting the electrochemical cell to a measuring circuit through contact pads on the electrical cell (col. 8, ll. 33-36), no details are provided on how the connection is made. In particular, no mention is made of whether the measuring circuit comprises a tongue plug.

Dietze et al. teach a biosensor comprising an electrochemical cell having contact pads and a measuring circuit (the abstract and Figure 1). The electrochemical cell is connected to the measuring circuit by tongue plugs, which rest on the contact pads of the electrochemical cell (Figure 6). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide tongue plugs as taught by Dietze et al. in the invention of Diebold et al. because spring-like pressure from the tongue plus will cause the tongue plugs to contact the contact pads so a good electrical connection will be made between the electrochemical cell and the measuring circuit and the electrochemical cell will be held in place.

Addressing claim 12, Diebold et al. teaches a biosensor for use in determining a concentration of a component in an aqueous liquid sample, the biosensor comprising

(a) a thin layer electrochemical cell, the cell comprising

(i) an electrically resistive sheet comprising an aperture wherein the aperture defines a working electrode area in the cell;

(ii) a first electrode layer covering the aperture on a first side of the sheet;

(iii) a second electrode layer covering the aperture on a second side of the sheet; and

(b) a measuring circuit.

See the abstract; Figures 1-6; and col. 8, ll. 15-36.

Although Diebold et al. discloses connecting the electrochemical cell to a measuring circuit through contact pads on the electrical cell (col. 8, ll. 33-36), no details are provided on how the connection is made. In particular, no mention is made of whether the measuring circuit comprises a tongue plug.

Dietze et al. teaches a biosensor comprising an electrochemical cell having contact pads and a measuring circuit (the abstract and Figure 1). The electrochemical cell is connected to the measuring circuit by tongue plugs, which rest on the contact pads of the electrochemical cell (Figure 6). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide tongue plugs as taught by Dietze et al. in the invention of Diebold et al. because spring-like pressure from the tongue plugs will cause the tongue plugs to contact the contact pads so a good electrical connection will be made between the electrochemical cell and the measuring circuit and the electrochemical cell will be held in place.

8. Claims 17, 19, 22-25, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Elko et al. (US 5,388,163).

Addressing claim 17, Diebold et al. teaches an apparatus for determining a concentration of a reduced form or an oxidized form of a redox species in a liquid sample, the apparatus comprising

(a) a hollow electrochemical cell having a working electrode and a counter electrode wherein the working electrode is closely spaced to the counter electrode;

(b) means for applying an electric potential difference between the electrodes; and

(c) means for electrochemically determining the concentration of the reduced form or the oxidized form of the redox species in the liquid sample

See the abstract; Figures 1-6; col. 8, ll. 15-36; and col. 10, ll.14-53.

Although Diebold et al. teaches that the working electrode is closely spaced to the counter electrode (since these electrodes are separated by a MYLAR film which defines, in part, a capillary space), Diebold et al. does not mention whether the working electrode and counter electrode are spaced apart by less than 500 μm. However, as seen from Elko et al., for example, MYLAR as thin as 2 μm was available at the time of the invention and used as a backing layer to a conductive layer in forming electrodes (col. 3, ll. 48-56). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a thin MYLAR layer, for example, less than 500 μm thick, to better accommodate the expected sample volume. In other words, since the MYLAR spacer in Diebold et al. defines the sample capillary diameter and separates the working and counter electrodes, the thickness of the spacer will be based on the

expected sample volume and will also determine the spacing between the working and counter electrodes.

Addressing claim 19, for the claimed socket region and contact areas note elements 41, 45, 9, and 3 in Figure 5.

Addressing claim 22, a substantially flat strip having a notch through the entire thickness to form a sample introduction aperture or passage is shown in Figure 5 (elements 43, 44, and 49).

Addressing claims 23 and 24, it should first be noted that claims 23 and 24 of the instant application only provide for intended use. Thus, since these claims do not further structurally modify the invention of claim 17 of the instant application, the rejection of claim 17 above also apples to claims 23 and 24. In any event, Diebold et al. teaches an embodiment especially adapted for measuring glucose in blood (col. 12, ln. 33 – col. 13, ln. 8).

Addressing claim 25, Diebold et al. teaches a method for determining a concentration of a reduced form or an oxidized form of a redox species in a liquid sample, the method comprising

(a) providing a hollow electrochemical cell having a working electrode and a counter electrode wherein the working electrode is closely spaced to the counter electrode;

(b) applying an electric potential difference between the electrodes; and

(c) electrochemically determining the concentration of the reduced form or the oxidized form of the redox species in the liquid sample

See the abstract; Figures 1-6; col. 8, ll. 15-36; col. 10, ll.14-53; and col. 12, ln. 35 – col. 12, ln. 27.

Although Diebold et al. teaches that the working electrode is closely spaced to the counter electrode, since these electrodes are separated by a MYLAR film which defines, in part, a capillary space, Diebold et al. does not mention whether the working electrode and counter electrode are spaced apart by less than 500 μm. However, as seen from Elko et al., for example, MYLAR as thin as 2 μm was available at the time of the invention and used as a backing layer to a conductive layer in forming electrodes (col. 3, ll. 48-56). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a thin MYLAR layer, for example, less than 500 μm thick, to better accommodate the expected sample volume. In other words, since the MYLAR spacer in Diebold et al. defines the sample capillary diameter and separates the working and counter electrodes, the thickness of the spacer will be based on the expected sample volume and will also determine the spacing between the working and counter electrodes.

Addressing claim 27, for the claimed socket region and contact areas note elements 41, 45, 9, and 3 in Figure 5.

Addressing claims 28 and 29, that measuring circuit comprises an automated instrument for applying an electric potential to the electrodes, detecting an electrical signal from the

electrochemical cell, and relating the electrochemical signal to the concentration of the component in the aqueous sample is implied by col. 13, ll. 9-16, which teaches that the measuring circuit is adapted to apply an algorithm relating the measured current to analyte concentration.

Addressing claim 30, a substantially flat strip having a notch through the entire thickness to form a sample introduction aperture or passage is shown in Figure 5 (elements 43, 44, and 49).

Addressing claims 31 and 32, it should first be noted that claims 31 and 32 of the instant application only provide for intended use. Thus, since these claims do not further structurally modify the invention of claim 25 of the instant application, the rejection of claim 25 above also applies to claims 31 and 32. In any event, Diebold et al. teaches an embodiment especially adapted for measuring glucose in blood (col. 12, ln. 33 – col. 13, ln. 8).

9. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Elko et al. (US 5,388,163) as applied to claims 17, 19, 22-25, and 27-30 above, and further in view of Dietze et al. (US 5,282,950).

Addressing claim 20, Diebold et al. teach an apparatus for determining a concentration of a reduced form or an oxidized form of a redox species in a liquid sample, the apparatus comprising

(a) a hollow electrochemical cell having a working electrode and a counter electrode wherein the working electrode is closely spaced to the counter electrode;

(b) means for applying an electric potential difference between the electrodes; and

(c) means for electrochemically determining the concentration of the reduced form or the oxidized form of the redox species in the liquid sample

See the abstract; Figures 1-6; col. 8, ll. 15-36; and col. 10, ll. 13-53.

Although Diebold et al. teaches that the working electrode is closely spaced to the counter electrode, since these electrodes are separated by a MYLAR film which defines, in part, a capillary space, Diebold et al. does not mention whether the working electrode and counter electrode are spaced apart by less than 500 μm. However, as seen from Elko et al., for example, MYLAR as thin as 2 μm was available at the time of the invention and used as a backing layer to a conductive layer in forming electrodes (col. 3, ll. 48-56). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a thin MYLAR layer, for example, less than 500 μm thick, to better accommodate the expected sample volume. In other words, since the MYLAR spacer in Diebold et al. defines the sample capillary diameter and separates the working and counter electrodes, the thickness of the spacer will be based on the expected sample volume and will also determine the spacing between the working and counter electrodes.

Although Diebold et al. in view of Elko et al. discloses connecting the electrochemical cell to a measuring circuit through contact pads on the electrical cell (col. 8, ll. 33-36), no details are provided on how the connection is made. In particular, no mention is made of whether the measuring circuit comprises a tongue plug.

Dietze et al. teaches a biosensor comprising an electrochemical cell having contact pads and a measuring circuit (the abstract and Figure 1). The electrochemical cell is connected to the measuring circuit by tongue plugs, which rest on the contact pads of the electrochemical cell (Figure 6). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide tongue plugs as taught by Dietze et al. in the invention of Diebold et al. in view of Elko et al. because spring-like pressure will cause the tongue plugs to contact the contact pads so a good electrical connection will be made between the electrochemical cell and the measuring circuit and the electrochemical cell will be held in place.

Addressing claim 21, that the means for electrochemically determining the concentration of the reduces form or the oxidized form of the redox species in the liquid sample comprises an automated instrument for detecting an electrical signal from the electrochemical cell and relating the electrochemical signal to the concentration of the component in the aqueous sample is implied by col. 13, ll. 9-16, which teaches that the measuring circuit is adapted to apply an algorithm that relates the measured current to analyte concentration.

Allowable Subject Matter

10. Claims 18 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 18: Diebold et al. does not disclose means for determining a change in current, means for estimating a magnitude of the steady state current, and means for obtaining from the change in current with time and the magnitude of the steady state current, a value indicative of the concentration of the reduced form or the oxidized form of the redox species, as claimed. Diebold et al. applies an unspecified algorithm to the measured current to determine the analtye concentration (col. 13, ll. 9-16);

b) Claim 26: Diebold et al. does not disclose determining a change in current, estimating a magnitude of the steady state current, and obtaining from the change in current with time and the magnitude of the steady state current, a value indicative of the concentration of the reduced form or the oxidized form of the redox species, as claimed. Diebold et al. applies an unspecified algorithm to the measured current to determine the analyte concentration (col. 13, ll. 9-16);

Information Disclosure Statement

12. Applicant is requested to provide copies of the following documents, which were cited in the IDS of August 08, 2001, but not found in the instant application and related applications listed in that IDS:

a) AU A31042/93 ;

b) JP466112 A ;

c) SU 1351-627 A ;

d) JP 62 22874 ;

e) AU-A 54873/94; and

f) WO 00/20626

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola